REMARKS

Pending claims

New claims 22-41 are currently pending in this National Stage Application, the remaining claims (1-21) having been canceled herein. New claims 22-36 are substantially the same as, although of different scope from, original claims 1-12 and 20-21, and basis for their addition may be found in original claims 1-12 and 20-21. Basis for new claims 38-41 may be found in the specification at, for example, page 11, lines 11-15; page 12, lines 7-10; page 35, lines 14-15; page 36, line 28 to page 37, line 4; and Example XII which appears at page 44, line 1-20.

No new matter is added thereby.

For the Examiner's convenience, the following Table illustrates the correspondence of the prior canceled claims with the presently pending claims:

Group Number (Description)	**Original Claims**	**New Claims**
I (a polypeptide, the polynucleotide encoding the polypeptide, and a method of making the polypeptide);	1-6; 10-12	22-31
II (an isolated and purified polynucleotide)	7-9	33, 34
III (a purified antibody)	14	32
IV (a purified agonist)	15	
V (a purified antagonist and methods for treating or preventing cancer or an immune disorder by administering it)	16, 18-19	
VI (a composition comprising a polypeptide of Claim 1 and a method for treating or preventing a neurological disorder by administering it)	13, 17	
VII (a method for detecting a polynucleotide using complements of the polynucleotide of claim 3)	20-21	35-37

II* (microarrays wherein at least one element is a polynucleotide of claim 33; and methods of using the microarrays) *Applicants assert that these claims are properly included in Group II		38-41

Applicants reserve the right to prosecute non-elected subject matter in subsequent divisional applications.

Restriction Requirement

In the Restriction Requirement, the Examiner requested Applicants to elect one of the inventions summarized in the preceding table.

Applicants hereby elect, with traverse, to prosecute Group I, which includes and is drawn at least to new claims 22-31.

The Examiner further asserts that

> "The separate polypeptides and polynucleotides bear distinct structural or biochemical properties as substantiated by the separate SEQ ID numbers. Therefore, each disclosed patentably distinct poypeptide and polynucleotide is considered a separate invention."

However, the Examiner did not explicitly require Applicants to elect a single polypeptide or polynucleotide for further Examination. Nonetheless, in order to expedite prosecution, Applicants hereby elect, again with traverse, to prosecute the claims of Group I with respect to SEQ ID NO: 6 and SEQ ID NO:12.

Applicants traverse the above elections for at least the following reasons.

Applicants reserve the right to prosecute the subject matter of non-elected claims in subsequent divisional applications.

The unity of invention standard ***must*** be applied in national stage applications

Section 1850 of the Manual of Patent Examining Procedure (original 8th edition, published August, 2001) (hereinafter "MPEP") provides:

> ... [W]hen the Office considers international applications ... during the national stage as a

> Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111....
>
> In applying PCT Rule 13.2 to ... national stage applications under 35 U.S.C. 371, examiners should consider for unity of invention all the claims to different categories of invention in the application and permit retention in the same application for searching and/or preliminary examination, claims to the categories which meet the requirements of PCT Rule 13.2....

Id at page 1800-60 to -61.

MPEP section 1893.03(d) reiterates the Examiner's obligation to apply the Unity of Invention standard PCT Rule 13.2 instead of U.S. restriction/election of species practice:

> Examiners are reminded that unity of invention (not restriction) practice is applicable ... in national stage (filed under 35 U.S.C. 371) applications.

Id at page 1800-149, column 1.

Unity of invention exists with respect to dependent claims in the same claim category as the independent claim from which they depend

MPEP section 1850(A) and 1893.03(d), which recite the provisions of paragraph (c) of Part 1 (entitled "Instructions Concerning Unity of Invention") of Annex B (entitled "Unity of Invention") to the Administrative Instructions Under the PCT, provides:

> **(A) Independent and Dependent Claims.**
>
> Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc.).
>
> (i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention....

See MPEP section 1850(A) at page 1800-61. See also MPEP Appendix AI at page 53.

In the present case, the claims of Group II (claims 33 and 34) both depend ultimately from claim 22, are both directed to compositions of matter, *i.e.*, to products, and both (implicitly)contain all

of the features of the independent claim. Therefore, they are properly considered in the present application along with the claims of Group I under Unity of Invention Practice.

Similarly, new claims 38 and 40-41, all of which are product claims which ultimately depend from claim 33 and which contain all of the features of independent claim 21, should also be considered in the present application.

Likewise, claim 32 (Group III) should also be considered herein, as it too is a product claim which depends from claim 21.

Unity of invention exists as between all of Applicants' claims

MPEP 1850 provides:

> Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art. The determination is made based on the contents of the claims as interpreted in light of the description and drawings. Annex B also contains examples concerning unity of invention.

Id at page 800-61.

MPEP 1893.03(d) similarly provides:

> A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. For example, a corresponding technical feature is exemplified by a key defined by certain claimed structural characteristics which correspond to the claimed features of a lock to be used with the claimed key. Note also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions as amended July 1, 1992 contained in Appendix AI of the MPEP.

Id at page 1800-149.

In the present case, unity of invention exists among all of Applicants' claims. The claimed polypeptide sequence of SEQ ID NO:6 and the claimed polynucleotide sequences encoding them (which includes SEQ ID NO:12) are corresponding technical features which are common to all of Applicants claims, which serve to technically interrelate all of Applicants' claims, and which define the contribution over the prior art made by each of them. Thus, Applicants' claims are linked to form a

single general inventive concept, and Applicants are therefore entitled to prosecute all of their pending claims in a single national stage application.

First, the claimed polypeptide and corresponding polynucleotide sequences are common to all of Applicant's claims, as one or both of those elements are either recited explicitly or are implicitly present by virtue of the claims depending from claim 21 and, in some cases, from claim 33.

Moreover, the claimed polypeptide and corresponding polynucleotide sequences serve to technically interrelate all of Applicants' claims. Applicants' composition of matter claims (21-29, 32, 33-34, 38, and 40-41) are drawn to either the sequences themselves (claims 21-26 and 33-34), to compositions of matter which comprise the sequences as one element (27-29, 38 and 40-41), or to compositions of matter wherein the claimed sequences functionally limit the claimed subject matter (claim 32). In Applicants' method claims, the claimed sequences serve as either the product of the claimed method and/or as a reagent for performing the method..

Therefore, the claimed polypeptide and polynucleotide sequences are corresponding technical features which are common to all of Applicants' claims, and which serve to technically interrelate them.

No Undue Burden to Search All of Applicants' Claims

Applicants further traverse the Restriction Requirement on the grounds that searching all of the claimed subject matter would not impose an undue burden on the examiner to evaluate the results, as those results would substantially overlap.

In particular, a search of the polypeptide of SEQ ID NO:6 would likely reveal, not only references citing that particular polypeptide, but also fragments and variants thereof. In addition, such a search is almost certain to uncover references describing the polynucleotides encoding that polypeptide, as well as antibodies which specifically bind it.

In this regard, despite the greater scope of claim 33 relative to claim 24, the results of a search of the polynucleotides recited in claim 33 would substantially overlap with those of a search conducted on polynucleotides of claims 24, 25 and 26, and therefore would not impose any undue addtitional burden on the Examiner.

Proper Markush Practice

The Examiner's attention is directed to the Patent Office's own requirements for Markush practice, set forth in the 8th edition of the M.P.E.P. (February 2003) at § 803.02 regarding restriction requirements in Markush-type claims:

> **PRACTICE RE MARKUSH-TYPE CLAIMS**
>
> If the members of the Markush group are **sufficiently few in number or so closely related** that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction.
>
> Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), **it is improper for the Office to refuse to examine that which applicants regard as their invention**, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, **unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility**.
>
> This subsection deals with Markush-type generic claims which include a plurality of alternatively usable substances or members. In most cases, a recitation by enumeration is used because there is no appropriate or true generic language. A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing claims of that nature, **the examiner may require a provisional election of a single species** prior to examination on the merits. The provisional election will be given effect in the event that the Markush-type claim should be found not allowable. Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable over the prior art, examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.
>
> As an example, in the case of an application with a Markush-type claim drawn to the

compound C-R, wherein R is a radical selected from the group consisting of A, B, C, D, and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD, or CE. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the nonelected species would be held withdrawn from further consideration. As in the prevailing practice, a second action on the rejected claims would be made final.

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry. [emphasis added]

As can be seen from the above, it is clear that the present Restriction Requirement does not meet the Patent Office's own requirements.

First, if the number of "members of the Markush group are **sufficiently few in number or so closely related** that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. **In such a case, the examiner will not follow the procedure described below and will not require restriction.**" Withdrawal of the restriction requirement as between the specific sequences each in the claims is required on that basis alone.

Second, "**it is improper for the Office to refuse to examine that which applicants regard as their invention**, unless the subject matter in a claim lacks unity of invention. ... Broadly, **unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that**

utility." Clearly, the polynucleotides (and their encoded polypeptides) of the instant invention share both a common utility and structural homology, based on their classification as human chemokine receptors.

Third, even if the claims could be considered to be "Markush-type generic claims which include a plurality of alternatively usable substances or members," it is further noted that the M.P.E.P states that "A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing claims of that nature, **the Examiner may require a provisional election of a single species** prior to examination on the merits." This clearly applies in the present case.

Finally, the Examiner's attention is directed to the M.P.E.P. at § 803.04 (Restriction - Nucleotide Sequences, EXAMPLES OF NUCLEOTIDE SEQUENCE CLAIMS) which states:

> Applications claiming more than ten individual independent and distinct nucleotide sequences in alternative form, such as set forth in example (A), will be subject to a restriction requirement. Only the ten nucleotide sequences selected in response to the restriction requirement and any other claimed sequences which are patentably indistinct therefrom will be examined.

The instant application claims exactly **six** polynucleotide sequences (SEQ ID NOs:7-12) and **six** polypeptide sequences (SEQ ID NOs:1-6) and the claims clearly should not be subject to an election of species requirement under the guidelines set forth in the M.P.E.P. at § 803.04. Therefore, it is respectfully submitted that, upon searching and examining SEQ ID NO:6 and finding no prior art over which SEQ ID NO:6 can be rejected, the Examiner must extend the search of the Markush-type claim to include the non-elected species.

REJOINDER

Additionally, the method claims of Group VII (claims 35-37) and claims 38 and 40-41 are entitled to rejoinder upon allowance of a product claim per the Commissioner's Notice in the Official Gazette of

March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)" which sets forth the rules, upon allowance of a product claim, for rejoinder of process claims covering the same scope of products. See also M.P.E.P. 821.04 as follows.

> Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. . . The claims to the nonelected invention will be withdrawn from further consideration under 37 C.F.R. 1.142. . . . However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Thus, Applicants request reconsideration and withdrawal of the Restriction Requirement and concurrent examination of Groups II-VII, as well as claims 38-41, along with the claims of Group I, in this single application.

CONCLUSION

In light of the above amendments and remarks, Applicants submit that the present application is fully in condition for allowance, and request that the Examiner withdraw the outstanding objections/rejections. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact the undersigned at the number listed below.

Please charge Deposit Account No. **09-0108** in the amount of **$420.00** as set forth in the enclosed fee transmittal letter. If the USPTO determines that an additional fee is necessary, please charge any required fee to Deposit Account No. 09-0108.

Respectfully submitted,

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